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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,676	01/04/1999	DAVID WALLACH	WALLACH=21	8997
1444	7590	09/21/2006	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EPFS FORD, JANET L	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/155,676

Applicant(s)

WALLACH ET AL.

Examiner

Janet L. Epps-Ford

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-16, 20-22, 43, 44, 46, 47, 49, 50, 53-60, 62-71, 73-75 and 77-79 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47, 62-64, 70 and 71 is/are allowed.
- 6) ☒ Claim(s) 13-16, 20-22, 43, 44, 49, 54, 55, 59, 60 and 69 is/are rejected.
- 7) ☒ Claim(s) 46, 50, 53, 56-58, 65-68, 73-75 and 77-79 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 13-16, 20-22, 43-44, 46-47, 49-50, 53-60, 62-71, 73-75, 77-79 are presently pending.
3. The rejection of claims 45-46 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment.

#### ***Claim Rejections - 35 USC § 112-Description***

4. Claims 13-16, 20-22, 43-44, 49, 54-55, 59-60, and 69 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Official Action mailed 9-05-02, and those set forth in the Official Action mailed 6-27-03.

Applicant's arguments filed 7-05-06 have been fully considered but are not persuasive. Applicants traverse the instant rejection by means of amending the claims. Specifically Applicants argue:

"[C]aim 69 has now been amended to make explicit that the fragment of part (c) must consist of an amino acid sequence of a fragment of the amino acid sequence of SEQ ID NO:2, and amino acid sequence encoded by the nucleotide sequence of SEQ ID NO:6, or the amino acid sequence of SEQ ID NO:5, which fragment binds to TRAF2

and either inhibits or increases the activity of NF- $\kappa$ B. Accordingly, this language cannot comprehend totally unrelated sequences.

Accordingly, it is believed that this amendment now obviates the 35 U.S.C. §112 rejection of claim 69 and all those claims dependent therefrom. Reconsideration and withdrawal thereof are therefore respectfully urged."

Contrary to Applicant's assertions, the current amendment to the claims does not obviate the pending rejection. Applicants' own specification confirms the need for further experimentation to identify the full scope of polypeptides encompassed by the instant claims. For example, in paragraph [0211] of the specification the following is disclosed:

[0211] As mentioned above, overexpression of NIK in 293  
EBNA cells induced NF- $\kappa$ B to an even greater extent than  
overexpression of TRAF2, but overexpression of the partial NIK  
15 (NIK 624-947) did not bring about NF- $\kappa$ B activation. In  
addition, the above noted NIK analog/mutain NIK KK429-430AA  
also did not bring about NF- $\kappa$ B activation when overexpressed  
in these cells. Thus, induction of NF- $\kappa$ B by NIK depends on an  
intact kinase function of NIK. In contrast, RIP (see Figs.  
20 2A-B) which also has a kinase domain can still induce NF- $\kappa$ B  
activation when its kinase activity is abolished by mutation.

The passage above clearly states that Applicants were unable to identify any fragments of NIK that would function to activate the expression of NF- $\kappa$ B. Applicants were only able to achieve NF- $\kappa$ B activation by using the intact NIK polypeptide. In regards to NF- $\kappa$ B inhibiting NF- $\kappa$ B activity, the specification discloses that the NIK partial clone 10,

amino acids 624-947, and NIK\* KK429-430AA did not result in NF- $\kappa$ B activation. Therefore, apart from disclosure of the full length NIK sequence, the partial NIK clone and the NIK\* mutant, there is no guidance for modifying these sequences to produce fragments or derivatives said fragments which function to increase or inhibit NF- $\kappa$ B activity. As stated in the prior Office Action, there is no clear structural correlation between the members of the claimed genus of fragments and the asserted function. The members of the claimed genus encompass polypeptides that have opposite activity, namely those that either inhibit or increase the activity of NF- $\kappa$ B. The genus of polypeptides comprising fragments having these opposing activities would be expected to be broader than a genus of polypeptides that have the same function, as indicated in Example 14 of the training materials. Therefore, contrary to Applicant's assertions, the logic used in Example 14 of the examiner training materials is not applicable in the instant scenario. Moreover, the genus of "activities" encompassed by the instant claims is so nebulous that the "activities" of NF- $\kappa$ B could possibly encompass a broad range of undefined activities not set forth in the specification as filed, such that the skilled artisan would not be able to discern which particular activity is either increased or inhibited by the claimed polypeptide comprising said fragments.

Applicant's arguments do not take the place of evidence that Applicant's were in possession of the full scope of the claimed invention at the time of filing of the instant application.

***Status of Applicant Initiated Interference***

5. As stated in the prior Office Action: On 2-09-01 Applicants sought to initiate an interference between the current application and US Patents 5,843,721 and 5,844,073, wherein the proposed count was claim 3 or 4 of US 5,843,721, or claim 54 of the instant application; or all of claims 1-15 of 5,843,721 and at least claim 54 of the instant application. Additionally, in the Remarks section of the reply filed 2-09-01, Applicants stated that claims 65-68 have been added in anticipation of an interference proceeding with US Patents 5,843,721 and 5,844,073. First it is noted that the prior indication of allowability for claim 54 is withdrawn, therefore the initiation of interference proceedings will be postponed until the indication of allowability of all pending claims. If Applicants wish to file a continuation claiming only the allowable subject matter in the instant application, or cancel all non-allowable claims in the instant application, interference proceedings can then be initiated. However, until all issues are resolved in the instant application the prosecution of this application will continue, and the interference initiation will be postponed.

***Conclusion***

6. Claims 47, 62-64, and 70-71 are allowable.

7. Claims 46, 50, 53, 56-58, 65-68, 73-75, and 77-79 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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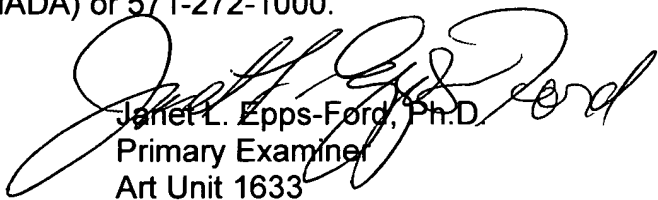
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Janet L. Epps-Ford, Ph.D.  
Primary Examiner  
Art Unit 1633

JLE